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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/583,335

02/15/2007

Shuxin Li

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EXAMINER

MURRAY, JEFFREY H

ART UNIT

PAPER NUMBER

1624

NOTIFICATION DATE

DELIVERY MODE

07/09/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

SUGHRUE@SUGHRUE.COM

Office Action Summary	Application No. 10/583,335	Applicant(s) LI ET AL.	
	Examiner JEFFREY H. MURRAY	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-12 and 21-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-12 and 21-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to an office action filed on February 28, 2008. There are twelve claims pending and twelve claims under consideration. Claims 1-6 and 13-20 have been cancelled. Claims 21-26 are new. This is the second action on the merits. The application concerns highly selective phosphodiesterase V inhibitors, pyrazolopyrimidinethione derivatives, and salts and solvates thereof, for preventing and/or treating impotence and frigidity, and their preparation methods and medical applications.

Status of Rejections

3. Claims 6 and 13-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The rejection against claim 6 and 13-19 are moot, in light of the cancellation of such claims therefore the rejection of Claims 6 and 13-19 are hereby withdrawn.

4. Claims 13-20 are rejected under 35 U.S.C. 112, second paragraph, as failing to comply with the definiteness requirement. The rejection against claims 13-20 are moot, in light of the cancellation of such claims therefore the rejection of Claims 13-20 are hereby withdrawn.

5. Claims 1, 2, 4 and 5 are rejected under 35 U.S.C. 103, as failing to comply with the nonobviousness requirement. The rejection against claims 1, 2, 4 and 5 are moot, in light of the cancellation of such claims therefore the rejection of Claims 1, 2, 4 and 5 are hereby withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior office action.

New Rejections

Claim Rejections - 35 USC § 103

6. Claims 7-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lu et. al. (CN 1472210) in view of *Graver Tank & Mfg. Co. v. The Linde Air Products Co.*, (USSC 1950) 339 US 695, 85 USPQ 328. The current application recites a variety of specific novel substituted pyrazolopyrimidinethione compounds and compositions that

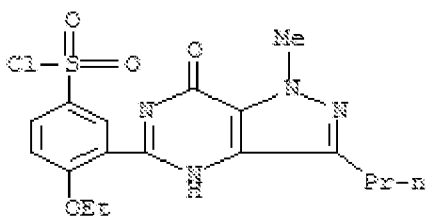
Art Unit: 1624

can be used as phosphodiesterase V inhibitors. These compounds all contain a pyrazolopyrimidinethione core with various substituents.

Lu et. al., teaches how to prepare a group of compounds which are similar in scope to the current application. Within Lu et. al., the same core structure is present with only one difference. The core of Lu et. al. is a pyrazolopyrimidinone, which contains a carbonyl group in the 4-position, whereas the present invention teaches a thione in the 4-position. Both the current application and Lu et. al. are being used as a treatment for impotence.

Lu, et. al. teaches the following reagent (RN 139756-22-2) and final product (RN 496835-35-9) in the process:

RN 139756-22-2 CAPLUS
CN Benzenesulfonyl chloride, 3-(6,7-dihydro-1-methyl-7-oxo-3-propyl-1H-pyrazolo[4,3-d]pyrimidin-5-yl)-4-ethoxy- (CA INDEX NAME)

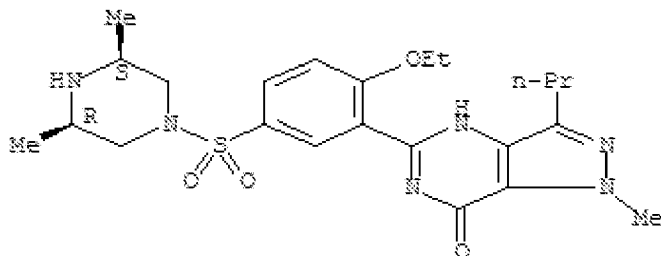


Art Unit: 1624

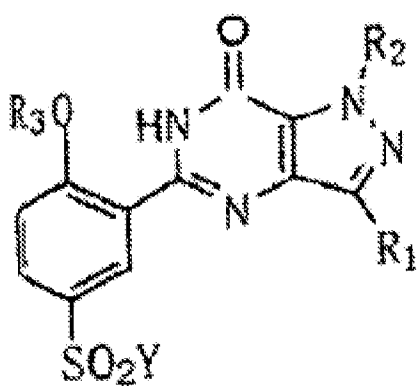
RN 496835-35-9 CAPLUS

CN 7H-Pyrazolo[4,3-d]pyrimidin-7-one, 5-[5-[[[(3R,5S)-3,5-dimethyl-1-piperazinyl]sulfonyl]-2-ethoxyphenyl]-1,6-dihydro-1-methyl-3-propyl-, rel- (CA INDEX NAME)

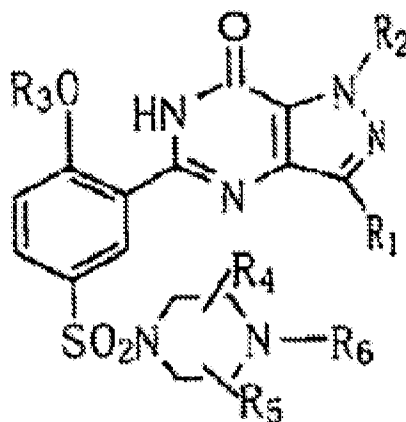
Relative stereochemistry.



The current application teaches the following general reagent (V) and final product (VI) in the process:



(V)

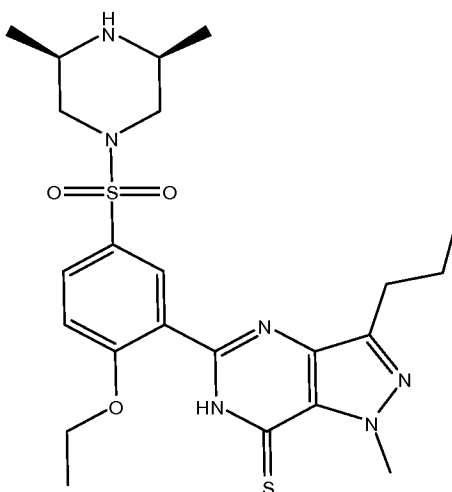


(VI)

The current application teaches and claims the following final compound:

5-[2-ethoxy-5-(cis-3,5-dimethylpiperazin-1-sulfonyl)phenyl]-1-methyl-3-n-propyl-1,6-dihydro-7H-pyrazolo[4,3-d]pyrimidin-7-one;

Which has the following structure:



Which is simply a keto-enol tautomer of the identical compound of the Lu, et al. patent but for the thione instead of a carbonyl group off of the pyrazolopyrimidines ring.

The court decision of *Graver Tank & Mfg. Co. v. The Linde Air Products Co.*, (USSC 1950) 339 US 695, 85 USPQ 328 teaches that the important factor in determining a test for equivalency in a prior art document is whether a person who is reasonably skilled in the art would recognize the equivalency.

Relating the information from *Graver Tank & Mfg. Co. v. The Linde Air Products Co.*, (USSC 1950) 339 US 695, 85 USPQ 328 to Lu et. al. publication, it would have been obvious for a person of ordinary skill in the art to try replacing the carbonyl derivative in the 4-position with a thione derivative in the same position. Sulfur and oxygen are well known in the chemical arts to have similar properties. For example, both elements fall within the same family in the periodic table of the chemical elements. As atoms, both oxygen and sulfur contain the same valence number, similar chemical properties and numerous chemical literature has suggested the attempted use of a thiol over an alcohol or a thiourea in place of a urea and vice versa. Due to the numerous

Art Unit: 1624

chemical property similarities of oxygen and sulfur, this substitution would be attempted by anyone skilled in the art.

The claims above are obvious because the substitution of one known element for another (sulfur for oxygen) would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

7. Claims 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baoshun et. al. (WO 2003016313) in view of *Graver Tank & Mfg. Co. v. The Linde Air Products Co.*, (USSC 1950) 339 US 695, 85 USPQ 328. The current application recites a variety of specific novel substituted pyrazolopyrimidinethione compounds and compositions that can be used as phosphodiesterase V inhibitors. These compounds all contain a pyrazolopyrimidinethione core with various substituents.

Baoshun et. al., teaches a group of compounds which are similar in scope to the current application. Within Baoshun et. al., the same core structure is present with only one difference. The core of Baoshun et. al. is a pyrazolopyrimidinone, which contains a carbonyl group in the 4-position, whereas the present invention teaches a thione in the 4-position. Both the current application and Baoshun et. al. are being used as a treatment for impotence.

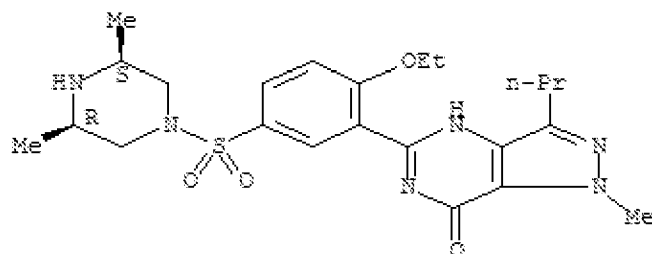
Baoshun, et. al. teaches the following compound:

Art Unit: 1624

RN 496835-35-9 CAPLUS

CN 7H-Pyrazolo[4,3-d]pyrimidin-7-one, 5-[5-[(3R,5S)-3,5-dimethyl-1-piperazinyl]sulfonyl]-2-ethoxyphenyl]-1,6-dihydro-1-methyl-3-propyl-, rel-
(CA INDEX NAME)

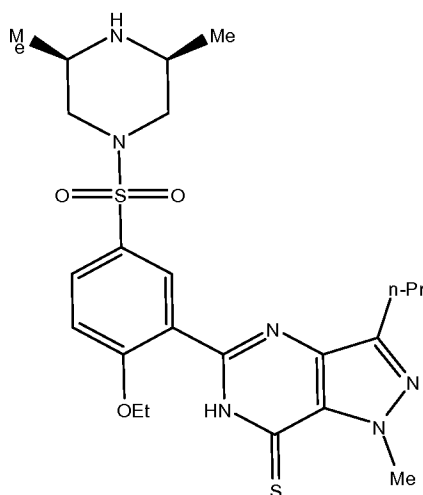
Relative stereochemistry.



The current application teaches the following compound:

5-[2-ethoxy-5-(cis-3,5-dimethylpiperazin-1-sulfonyl)phenyl]-1-methyl-3-n-propyl-1,6-dihydro-7H-pyrazolo[4,3-d]pyrimidin-7-thione;

Which has the following structure:



The court decision of *Graver Tank & Mfg. Co. v. The Linde Air Products Co.*,
(USSC 1950) 339 US 695, 85 USPQ 328 teaches that the important factor in

Art Unit: 1624

determining a test for equivalency in a prior art document is whether a person who is reasonably skilled in the art would recognize the equivalency.

Relating the information from *Graver Tank & Mfg. Co. v. The Linde Air Products Co.*, (USSC 1950) 339 US 695, 85 USPQ 328 to Baoshun et. al. publication, it would have been obvious for a person of ordinary skill in the art to try replacing the carbonyl derivative in the 4-position with a thione derivative in the same position. Sulfur and oxygen are well known in the chemical arts to have similar properties. For example, both elements fall within the same family in the periodic table of the chemical elements. As atoms, both oxygen and sulfur contain the same valence number, similar chemical properties and numerous chemical literature has suggested the attempted use of a thiol over an alcohol or a thiourea in place of a urea and vice versa. Due to the numerous chemical property similarities of oxygen and sulfur, this substitution would be attempted by anyone skilled in the art.

The claims above are obvious because the substitution of one known element for another (sulfur for oxygen) would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Conclusion

8. Claims 7-12 and 21-26 are rejected.

Art Unit: 1624

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey H. Murray whose telephone number is (571) 272-9023. The examiner can normally be reached on Mon-Thurs. 7:30-6pm EST.

10. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1624

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a US PTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey H Murray/
Examiner, Art Unit 1624

**/James O. Wilson/
Supervisory Patent Examiner, Art Unit 1624**